JUN 21 2000

AUREX
P.O. Box 509 Edenvale 1610
Republic of South Africa
Telephone: +27 (11) 609-8640
Telefax: +27 (11) 452-3918

K001480

# 510 (k) Summary

| | |
|---|---|
| Trade name: | Aurecast 40B |
| Common name: | Dental casting alloy |
| Classification name: | Gold based alloys and precious metal alloys for clinical use |
| Classification number: | EJT |
| Legally marketed device: | Jelenko Midas |
| Description of the device: | Medium gold casting alloy |
| Intended use of the device: | Type IV restoration |

**Summary of the technological characteristics**
Test methods applied: as in ANSI/ADA 5 and ISO 8891

Comparison of composition:

| ALLOY | | COMPOSITION (WEIGHT%) | | | | | |
|---|---|---|---|---|---|---|---|
| | Name | Au | Ag | Pd | Cu | Ru | Zn |
| Legal | Jelenko Midas | 46.0 | 39.5 | 6.0 | 7.5 | - | 1.0 |
| New | Aurecast 40B | 40.0 | 40.0 | 8.0 | 11.95 | 0.05 | - |

Comparison of physical and mechanical properties

| ALLOY | Melting point range (°C) | | Hardness (Vickers 5/30) | | Yield strength (Mpa) | | Elongation (%) | | Density (g/cm3) |
|---|---|---|---|---|---|---|---|---|---|
| Name | solid | liquid | hard | soft | hard | soft | hard | soft | |
| Jelenko Midas | 860 | 960 | 231 | 138 | 240 | 590 | 13 | 30 | 12.8 |
| Aurecast 40B | 920 | 940 | 220 | 180 | 630 | 355 | 3 | 15 | 11.5 |

**Discussion**
The concentration of the main matrix elements Au, Ag and Pd is very close to each other in both alloys. The slightly higher Cu content results in improved mechanical properties for the new alloy.

**Conclusion**
The main elements and their concentration are up to 99 % very similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2000

Mr. J.D. Davis
Chief Executive Officer
Aurex SA Pty Ltd.
24 Plantation Road, Eastleigh
Edenvale, Gauteng, Rep South Africa 1610

Re: K001480
Trade Name: Aurecast 40 B
Regulatory Class: II
Product Code: EJT
Dated: April 17, 2000
Received: May 11, 2000

Dear Mr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Patricia Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001480

Device Name: AURECAST 40 B

Indications For Use:

Dental casting alloy for metallic restorations.
It cannot be used in combination with dental porcelains.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001480

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)